IS 11628 (1986): Agar Impression Material [MHD 8: Dentistry]

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*Indian Standard*

# SPECIFICATION FOR AGAR IMPRESSION MATERIAL

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INDIAN STANDARDS INSTITUTION
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
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# *Indian Standard*

# SPECIFICATION FOR AGAR IMPRESSION MATERIAL

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# *Indian Standard*

# SPECIFICATION FOR AGAR IMPRESSION MATERIAL

## 0. FOREWORD

**0.1** This Indian Standard was adopted by the Indian Standards Institution on 27 January 1986, after the draft finalized by the Dental Materials Sectional Committee had been approved by the Chemical Division Council.

**0.2** In the preparation of this standard, considerable assistance has been derived from ISO 1564-1976 'Agar impression material', issued by the International Organization for Standardization ( ISO ).

**0.3** For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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## 1. SCOPE

**1.1** This standard prescribes the requirements and methods of sampling and test for agar impression material for dental use.

## 2. REQUIREMENTS

**2.1 Description** — This material is in gel form containing a reversible agar hydrocolloid as a gel-forming ingredient. The material shall be uniform and free from foreign matter. When used according to manufacturer's directions it shall form a smooth plastic mass suitable for taking impressions in the mouth. The material, when used, shall not have an unpleasant odour or flavour.

**2.2 Freedom From Toxicity** — The material shall not contain poisonous ingredients in sufficient concentration to be harmful to human beings on actual application.

*Rules for rounding off numerical values ( *revised* ).

**2.3 Irritation** — The material, when used according to manufacturer's directions, shall not normally cause visible evidence of irritation of the normal oral mucosa, when softened by boiling in water (100°C), tempered to 40 to 50° C and used for making impressions.

**2.4 Extrusion** — The material, when prepared according to the directions of the manufacturer and tested in accordance with **A-2**, shall be capable of extrusion through a hollow needle or tube having an inside diameter not exceeding 0·6 mm.

**2.5 Compatibility with Gypsum** — The impression material shall impart a smooth surface to, and separate neatly from, a gypsum cast mould from unmodified alpha calcium sulphate hemihydrate. The cast poured against the agar impression according to **A-3** shall, for the full width of the specimen, reproduce the line 0·075 mm wide, on the test block shown in Fig. 1.

**2.6 Consistency** — The material shall remain sufficiently plastic, when heated in boiling water for 8 min in a metal mixing syringe or 10 min in the original container, and tempered according to the direction of the manufacturer, to permit its easy removal from the syringe or original container and adoptation to the impression tray. At a temperature of 43 to 50° C, the material shall not run out of an inverted perforated, metal tray, such as is commonly used for hydrocolloid impression materials, during an interval of 15 seconds.

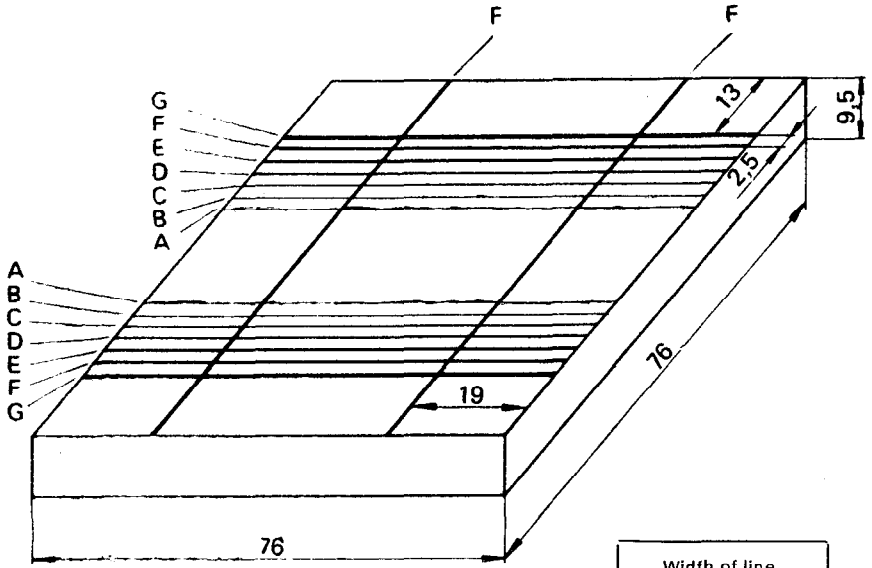
**2.7 Temperature of Gel Formation** — The temperature at which the plastic mass sets to a gel on cooling shall be not less than 37°C no more than 45°C when determined in accordance with **A-4**.

**2.8 Uniformity** — After boiling and tempering, and during setting of the material, the ingredients shall not segregate. The material so prepared shall be homogeneous, free from lumps and granules and the surface shall be smooth.

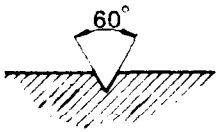
**2.9 Permanent Deformation** — The permanent deformation of the set material shall be not more than 1·5 percent, after a 10 percent strain is applied for 30 seconds when determined in the manner prescribed in **A-5**.

**2.10 Compressive Strength** — The compressive strength shall be not less than 0·2 $MN/m^2$ (approx 2 $kgf/cm^2$) when determined in the manner prescribed in **A-6**.

**2.11 Strain in Compression** — The strain shall be not less than 4 percent no more than 15 percent between a stress of 0·01 $MN/m^2$ (approx 0·1 $kgf/cm^2$) and a stress of 0·1 $MN/m^2$ (approx 1·0 $kgf/cm^2$) when determined in the manner precribed in **A-7**.




| Width of line | |
|---|---|
| A | 0·025 |
| B | 0·050 |
| C | 0·075 |
| D | 0·100 |
| E | 0·150 |
| F | 0·200 |
| G | 0·300 |




Cross-section of ruled lines

All dimensions in millimetres.

FIG. 1 BLOCK FOR DETAIL REPRODUCTION

**2.12 Manufacturer's Instructions** — The instructions for proportioning and manipulating shall include information regarding the following points:

a) The type of tray, syringe and needle recommended for use with the material;

b) The time and temperature requirements for softening and tempering the material in the original container and in the syringe;

c) The temperature at which the material should be inserted in the mouth;

d) The technique recommended for chilling the impression in the mouth;

e) The treatment of the impression during the interval between its withdrawal from the mouth and the preparation of the gypsum cast; and

f) A statement that the material contains a fungicide that will effectively prevent mould growth.

## 3. PACKING AND MARKING

**3.1 Packing** — The material shall be supplied in properly sealed containers made of such materials which shall not contaminate or permit contamination of the contents.

**3.2** Manufacturer's instructions for use shall accompany each package (*see* **2.12**).

**3.3 Freedom from Toxicity** — A certificate shall be furnished by the manufacturer stating that the material complies with the requirements of **2.2** along with each container.

**3.4 Marking** — Each container shall bear legibly and indelibly the following information:

a) Date of manufacture;

b) Net mass or volume — The minimum net contents expressed in millilitres or grams, shall be indicated on the respective containers:

c) Name of the manufacturer and/or his recognized trade-mark, if any; and

d) Batch number.

**3.4.1** Each container may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The ISI Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

## 4. SAMPLING

**4.1** The method of preparing samples of the material and criteria for conformity shall be as prescribed in Appendix B or as agreed to between the purchaser and the supplier.

# APPENDIX A

( *Clauses* 2.4, 2.5, 2.7, 2.9, 2.10 *and* 2.11 )

## METHODS OF TEST FOR AGAR IMPRESSION MATERIAL

### A-1. PREPARATION OF TEST SPECIMENS

**A-1.1** The test specimens shall be prepared in accordance with the instructions of the manufacturer as given in **2.12.**

**A-1.2 Ambient Conditions** — All physical tests shall be carried out at a temperature of 27 ± 2°C and a relative humidity between 55 to 75 percent.

**A-1.2.1** Condition test equipment and material in the testing room for not less than 10 h prior to testing.

### A-2. DETERMINATION OF EXTRUSION

**A-2.1 Apparatus** — A suitable syringe and needle as recommended by the manufacturer ( *see* **2.12** ) or syringe of the type commonly used to inject the material into a preparation fitted with a hollow needle of tube of inside diameter not more than 0·6 mm.

**A-2.2 Procedure** — Transfer 3 ml of the softened material in a syringe and temper according to the instructions of the manufacturer ( *see* **2.12** ). The force necessary for extrusion of the material from the syringe shall not exceed that which will readily allow accurate placement of the material into any required position.

### A-3. DETERMINATION OF COMPATIBILITY WITH GYPSUM

**A-3.1 Charactcristic of the Gypsum** — Use unmodified calcium sulphate hemihydrate; if required, add sufficient quantity of calcium sulphate dihydrate to adjust the time of setting to 10 ± 3 min to satisfy the conditions of setting given in **A-3.3.** When tested directly against the block shown in Fig. 1, the mix shall reproduce satisfactorily 0·050 mm wide line.

**A-3.2 Preparation of the Gypsum Slurry** — Add approximately 100 g of powder gradually over a period of 15 seconds to 30 ml of distilled water (*see* IS : 1070-1977*) in a mixing bowl. After allowing the powder to soak in water for 15 seconds, hand-spatulate the mix for one min with a flexible metal spatula of width 18 ± 1 mm.

**A-3.3 Determination of Gypsum Setting Time**

**A-3.3.1** *Apparatus*

**A-3.3.1.1** *Mould* — A cylindrical mould of diameter 25 mm and height 25 mm.

**A-3.3.1.2** *Vicat needle* — Mass 300 ± 0·5 g with a penetrating shaft of diameter 1 ± 0·5 mm and length approximately 50 mm.

**A-3.3.2** *Procedure* — Pour the slurry (*see* **A-3.2**) immediately into the cylindrical mould and determine the setting time with the Vicat needle. Lower the Vicat needle vertically until it touches the top of the specimen and then release to allow the needle to sink into the mixture. Make repeat trials in different areas of the specimen at intervals of one minute until the needle no longer penetrates to the bottom of the specimen. The setting time shall be the number of minutes that elapse from the beginning of the addition of the powder to the water until the needle fails to penetrate to the bottom of the specimen.

**A-3.4 Preparation of Agar Specimen**

**A-3.4.1** *Stainless Steel Test Block* — Similar block as shown in Fig. 1 of stainless steel, so that the intersection of the cross line and the 0·025 mm wide line is in the centre of the ring of the type specified in **A-5.2.**

**A-3.4.2** *Procedure* — Position the ring on the test block (*see* **A-3.4.1**) and slightly overfill the ring with the impression material. Place a flat plate on top of the ring and squeeze out the excess material. After 15 min, separate the ring with the impression material from the plate and the test block. Shake the impression by hand to remove the excess exudate.

**A-3.5 Preparation of Gypsum Cast**

**A-3.5.1** *Apparatus* — Microscope lamp or any other suitable source of light.

**A-3.5.2** *Conditioning Chamber* — Temperature 27 ± 2°C and relative humidity 100 percent.

*Specification for water for general laboratory used (*second revision*).

**A-3.5.3** *Procedure* — Pour gypsum slurry prepared as given in **A-2.3** and under gentle vibration, against the agar impression, prepared according to **A-3.4** within 2 min from the time, the impression is separated from the test block. Place the assembly in a conditioning chamber at 27 ± 2°C and 100 percent relative humidity for 30 min. Remove the gypsum cast and examine, without magnification, under low angle illumination with microscope lamp or any other suitable source of light, for surface finish and quality of impression of the 0·075 mm line. The reproduction of the 0·075 mm line shall be considered satisfactory if it is continuous for the full width of the ring.

## A-4. TEMPERATURE OF GEL FORMATION

**A-4.1 Apparatus** — The type of apparatus shall be essentially as shown in Fig. 2. This apparatus consists of a metal tary of approximate inside dimensions 100 mm × 28 mm × 20 mm with a drilled hole to accommodate a thermometer bulb, and a metal tube having an inside diameter of 10 mm and a wall thickness of approximately 1 mm.

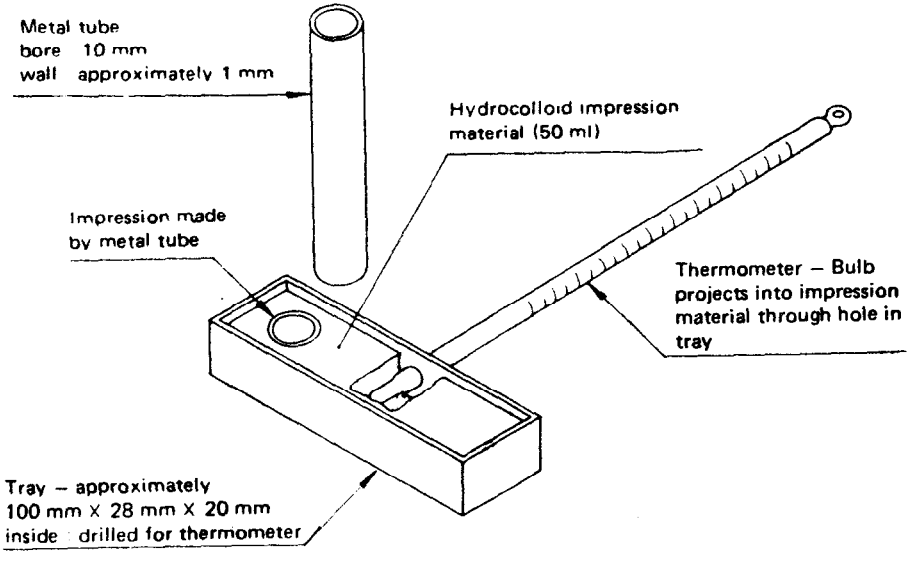



FIG. 2 EQUIPMENT FOR DETERMINING GELATION OF HYDROCOLLOID IMPRESSION MATERIALS

**A-4.2 Procedure** — Extrude into a small tray approximately 50 ml of the material, which has been softened and tempered in accordance with **2.12**, at a temperature of 50°C. Insert the thermometer into the material through the side hole of the tray. During the cooling of the

specimen from 50°C, at the rate of 1·5 ± 0·5°C per minute, insert the tube several times vertically into the material until the tube touches the floor of the tray, thus making a series of impressions. Withdraw the tube immediately each time. Near the gelation temperature, make trials every 0·5°C. Make final trials in that portion of the material lying near the thermometer bulb.

**A-4.3 Expression of Results** — The temperature of gel formation shall be the highest temperature at which the two concentric circles caused by the inside and outside surfaces of the indenting tube are clearly outlined and the material does not cling to the polished surface of the tube. Round off the average of three test results to the nearest degree Celsius.

## A-5. PERMANENT DEFORMATION CAUSED BY FIXED STRAIN

**A-5.1 Apparatus** — The type of apparatus shall be essentially as shown in Fig. 3. This apparatus consists of a ) dial indicator ( *B* ), graduated in 0·02 mm, mounted on a stable base and equipped with a screw ( *A* ) positioned in such a manner that sufficient force can be applied to the specimen to produce the required amount of strain, and a foot intended to exert the force on the specimen; b) lightweight plate which has to be placed on top of the specimen (*C*), another plate being inserted between the bottom of the specimen and the base of the apparatus.

**A-5.2 Preparation of Test Specimen** — Place a metal ring of inside diameter 30 mm and height 16 mm, on a flat glass or metal plate and fill the ring slightly more than one-half full with softened and tempered material. Insert a metal mould in the form of a cylinder of inside diameter 12·7 mm, outside diameter 25·4 mm and height 19 mm immediately inside the ring and force it into the material until the mould touches the plate and the material has exuded on to the top of the mould. Press a second flat glass or metal plate on top of the mould to remove the excess material. After 30 min, remove the specimen from the mould and place in conditioning chamber maintained at 27 ± 2°C and 100 percent relative humidity for 30 min. During the test, the specimen shall be protected with a loosely wrapped moistened gauge cloth to prevent excessive moisture losses.

**A-5.3 Procedure** — After one hour from the start of the mix, place a specimen, prepared as in **A-5.2**, in the testing instruments ( *see* **A-5.1** ). Place a lightweight plate on top of the specimen and contact this plate with the foot of the dial indicator. The force exerted by the plate and indicator shall be 0·50 ± 0·05 N ( approx 50 ± 5 gf ). Read the indicator 30 seconds after its foot contacts the plate and record this as reading *a*. Lower the foot of the indicator 1·9 mm by the screw, leave for

30 seconds, release and allow the specimen to rest under no load ( except that of the lightweight plate ) for 30 seconds. Then lower the dial indicator onto the plate for 30 seconds and take a second reading. Record this as reading *b*. Take the difference between readings *a* and *b*, divided by the original length of the specimen and multiplied by 100, as the percentage permanent deformation. Take the average permanent deformation of the three specimens.

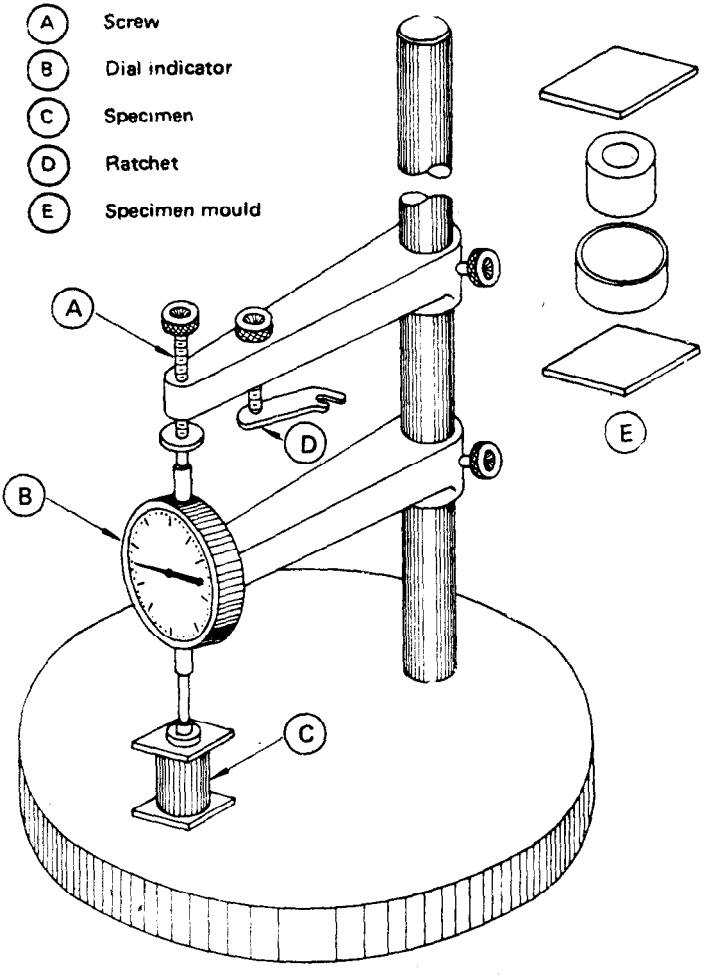



FIG. 3 INSTRUMENT FOR UNDER FIXED STRAIN PERMANENT DEFORMATION

## A-6. COMPRESSIVE STRENGTH

**A-6.1 Apparatus** — Any device for testing of compressive strength, accurate to 0·5 N ( approx 50 gf ).

**A-6.2 Procedure** — Test specimen as prepared under **A-5.2** shall be placed in the testing machine with a piece of heavy writing paper under and over the specimen, after one hour of its preparation and tested for compressive strength. Load the specimen continuously at a uniform rate of $100 \pm 20$ N/min ( approx $10 \pm 2$ kgf/min ) until the specimen fractures.

**A-6.3 Expression of Results** — Record the maximum load at fracture to nearest 0·5 N ( approx 50 gf ). Divide the maximum load by cross-sectional area of the mould and report the average strength of three specimens, in $MN/m^2$ ( or $kgf/cm^2$ ).

## A-7. STRAIN IN COMPRESSION

**A-7.1 Apparatus** — Any device having a dial indicator graduated in 0·02 mm, capable of producing the amount of compression required ( *see* Fig. 4 ).

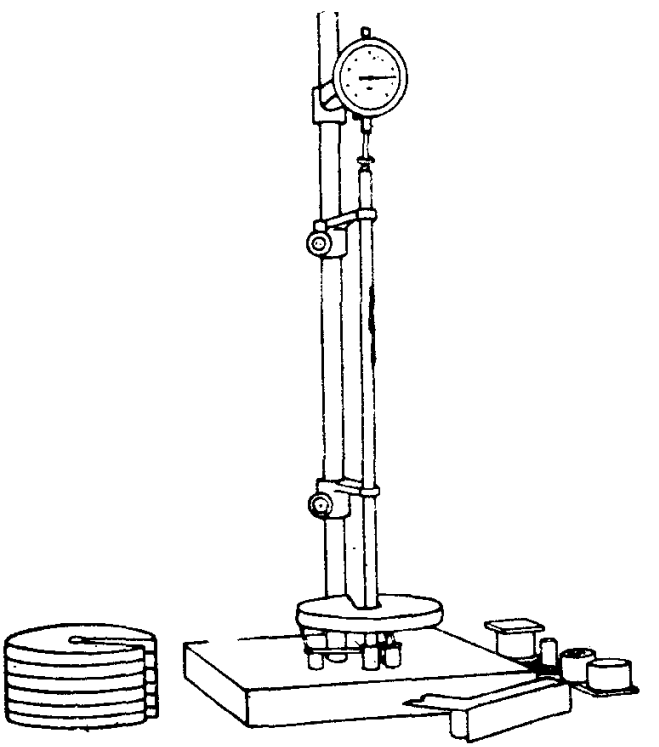


FIG. 4 INSTRUMENT FOR MEASURING STRAIN IN COMPRESSION

**A-7.2 Procedure** — One hour from the start of mixing, place a specimen prepared as specified in **A-5.2**, in measuring device described in **A-7.1** and subject it to a load calculated to produce a stress of 0·01 $MN/m^2$ ( approx 0·1 $kgf/cm^2$ ). After 30 seconds, read the dial indicator and record this reading as *a*. After 60 seconds, apply an additional load calculated to produce a total stress of 0·10 $MN/m^2$ ( approx 1·0 $kgf/cm^2$ ) during an interval of 10 seconds. After 30 seconds of initiation of the stress of 0·10 $MN/m^2$ ( approx 1·0 $kgf/cm^2$ ), take second reading on the dial, recording it as *b*.

**A-7.3 Expression of Results** — Record the difference between *a* and *b*. Divide the difference by the original length of the specimen, that is, the height of the mould used in forming it, and multiply by 100 to obtain percentage strain between the stresses of 0·01 and 0·1 $MN/m^2$ ( approx 0·10 and 1·0 $kgf/cm^2$ ). Calculate and report the average strain of three specimens.

# APPENDIX B

( *Clause* 4.1 )

## SAMPLING OF AGAR IMPRESSION MATERIAL

### B-1. GENERAL REQUIREMENTS OF SAMPLING

**B-1.0** In drawing, preparing, storing and handling test samples, the precautions and directions given in **B-1.1** to **B-1.7** shall be observed.

**B-1.1** Sample shall not be taken in an exposed place.

**B-1.2** The sampling instrument shall be neat and clean.

**B-1.3** Precautions shall be taken to protect the samples, the material being sampled, the sampling instrument and the containers for samples from adventitious contamination.

**B-1.4** To draw a representative sample, the contents of each container selected for sampling shall be mixed as thoroughly as possible by suitable means.

**B-1.5** The samples shall be placed in clean, dry, air-tight, glass or other suitable containers.

**B-1.6** The sample containers shall be of such sizes that they are almost completely filled by the sample.

**B-1.7** Each sample container shall be sealed air-tight with a suitable stopper after filling and marked with full details of sampling, the date of sampling and the year of manufacture of the material.

## B-2. SCALE OF SAMPLING

**B-2.1 Lot** — All the containers in a single consignment of the material drawn from a single batch of manufacture shall constitute a lot. If a consignment is declared or known to consist of different batches of manufacture, the containers belonging to the same batch shall be grouped together and each such group shall constitute a separate lot.

**B-2.1.1** Samples shall be tested from each lot for ascertaining conformity of the material to the requirements of this specification.

**B-2.2** The number of containers ($n$) to be chosen from the lot shall depend on the size of the lot ($N$) and shall be as given in Table 1.

**TABLE 1 NUMBER OF CONTAINERS TO BE SELECTED FOR SAMPLING**

| LOT SIZE $N$ | NUMBER OF CONTAINERS TO BE SELECTED $n$ |
|---|---|
| (1) | (2) |
| 3 to 50 | 3 |
| 51 ,, 200 | 4 |
| 201 ,, 400 | 5 |
| 401 ,, 650 | 6 |
| 651 ,, 1 000 | 7 |

**B-2.3** The containers to be selected for sampling shall be chosen at random from the lot and for this purpose, random number tables in accordance with IS : 4905-1968* shall be used. In case such tables are not available the following procedure may be adopted:

Starting from any container, count them as 1, 2, 3,....., $r$, and so on in a systematic manner, where $r$ is the integral part of $N/n$. Every $r$th container thus counted shall be withdrawn from the lot.

## B-3. TEST SAMPLES AND REFEREE SAMPLE

### B-3.1 Preparation of Test Samples

**B-3.1.1** Draw with an appropriate sampling instrument, a small portion of the material from different parts of each container selected

*Methods for random sampling.

(*see* Table 1). The total quantity of the material drawn from each container shall be sufficient to conduct the tests for all the characteristics given under 2 and shall be not less than 250 g.

**B-3.1.2** Thoroughly mix all portions of the material drawn from the same container. Out of these portions, equal quantities shall be taken from each selected container and shall be well mixed up together so as to form a composite sample weighing not less than 0·5 kg. This composite sample shall be divided into three equal parts, one for the purchaser, another for the supplier and the third for the referee.

**B-3.2 Referee Sample** — The referee sample consists of a composite sample marked for this purpose and shall bear the seal of the purchaser and the supplier. It shall be kept at a place agreed to between the purchaser and the supplier and shall be used in case of dispute between the two.

## B-4. TESTS

**B-4.1** Tests for all characteristics given in **2** shall be conducted on the composite sample.

## B-5. CRITERIA FOR CONFORMITY

**B-5.1** A lot shall be declared as conforming to this specification if the composite sample satisfies the requirements for each of the characteristics listed in **2**. If the requirements for any of the characteristics are not met, the lot shall be declared to have not satisfied the requirements of the specification.

# INTERNATIONAL SYSTEM OF UNITS ( SI UNITS

**Base Units**

| Quantity | Unit | Symbol |
|---|---|---|
| Length | metre | m |
| Mass | kilogram | kg |
| Time | second | |
| Electric current | ampere | A |
| Thermodynamic temperature | kelvin | K |
| Luminous intensity | candela | cd |
| Amount of substance | mole | mol |

**Supplementary Units**

| Quantity | Unit | Symbol |
|---|---|---|
| Plane angle | radian | rad |
| Solid angle | steradian | sr |

**Derived Units**

| Quantity | Unit | Symbol | Definition |
|---|---|---|---|
| Force | newton | N | 1 N = 1 $kg.m/s^2$ |
| Energy | joule | J | 1 J = 1 N.m |
| Power | watt | W | 1 W = 1 J/s |
| Flux | weber | Wb | 1 Wb = 1 V.s |
| Flux density | tesla | T | 1 T = 1 $Wb/m^2$ |
| Frequency | hertz | Hz | 1 Hz = 1 $c/s$ ($s^{-1}$) |
| Electric conductance | siemens | S | 1 S = 1 A/V |
| Electromotive force | volt | V | 1 V = 1 W/A |
| Pressure, stress | pascal | Pa | 1 Pa = 1 $N/m^2$ |